

## REMARKS

This Amendment responds to the final Office Action mailed on January 22, 2009. Claims 1, 3-9, 18-26, and 28-32 are pending. Claims 1, 6-9, 18, and 23 have been amended. Claim 27 has been cancelled. Claims 28 and 29 are withdrawn. Claims 30-32 are new. In view of the following remarks, as well as the foregoing amendments, Applicants submit that this application is in complete condition for allowance in this regard.

### **Rejections of Claims under 35 U.S.C. § 102**

#### **Claims 1, 3, 4, 6, 8, 18-20, 22-25 and 27 over Brown**

Claims 1, 3, 4, 6, 8, 18-20, 22-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 2,591,046 to Brown et al. (hereinafter *Brown*). The Examiner contends that *Brown* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1, as amended, sets forth “a piston disposed inside said sidewall of said barrel to define a fluid chamber between said piston and said second opening that is in fluid communication with said second opening”, and that a periphery of the piston “provides a fluid seal with said axial grooves to inhibit fluid leakage from said fluid chamber between said piston and said inwardly-facing surface as said piston is advanced toward said second opening to dispense the fluid from said fluid chamber through said second opening”.

In contrast, *Brown* discloses a syringe barrel (11) with grooves (25) that are localized axially over a short distance between the opposite open ends of the syringe barrel (11) near the center of the barrel (11). The grooves (25) serve to permit the fluid (30) to bypass the piston (16) and mix with a dry medication (29), but only when the syringe is used to advance the piston (16)

with the barrel (11) relative the location of the grooves (25). When the piston (16) experiences a loss of fluid seal with the grooves (25) and the inwardly-facing surface of the barrel (11), the grooves (25) present flow channels that permit the fluid (30) to flow past the piston (16) and mix with the dry medication (29). Moreover, the fluid chamber, which is between the piston (32) and the opening (13) from which the fluid is dispensed, is not in fluid communication with the opening (13). In addition, the grooves (25) in *Brown* are not contacted by the fluid when the fluid chamber is filled with fluid.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because of the aforementioned deficiencies, *Brown* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6, 8, 18-20, and 22-25 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Brown*.

Claims 1, 3, 4, 6, 8, 18-20, and 22-27 over *Bachynsky*

Claims 1, 3, 4, 6, 8, 18-20, and 22-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,971,953 to Bachynsky (hereinafter *Bachynsky*). The Examiner contends that *Bachynsky* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

As mentioned above, independent claim 1, as amended, sets forth “a piston disposed inside said sidewall of said barrel to define a fluid chamber between said piston and said second opening that is in fluid communication with said second opening”, and that a periphery of the piston “provides a fluid seal with said axial grooves to inhibit fluid leakage from said fluid chamber between said piston and said inwardly-facing surface as said piston is advanced toward said second opening to dispense the fluid from said fluid chamber through said second opening”.

In contrast, *Bachynsky* discloses a syringe barrel (11) with grooves (30) that are localized axially over a short distance between the openings at the opposite ends of the barrel (11) and near the center of the barrel (11). The grooves (30) serve to permit the stored fluid (23) to bypass the piston (32) and mix with a dry medication (24), but only when the piston (32) is advanced relative to the barrel (11) to the location of the grooves (30). When the piston (32) loses its fluid seal with the inwardly-facing surface of the barrel (11) and the grooves (30), the grooves (30) then function as flow channels to permit the fluid (23) to flow past the piston (32) and mix with the dry medication (24). Moreover, the fluid chamber, which is between the piston (32) and the opening (17) from which the fluid is dispensed, is not in fluid communication with the opening (17). In addition, the grooves (30) in *Bachynsky* are not contacted by the fluid when the fluid chamber is filled with fluid.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed

invention. Because of the aforementioned deficiencies, *Bachynsky* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6, 8, 18-20, and 22-26 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above.

Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Bachynsky*.

*Claims 1, 3, 4, 6-8, 18-20, 22-25, and 27 over Reinhard*

Claims 1, 3, 4, 6-8, 18-20, 22-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,788,670 to Reinhard et al. (hereinafter *Reinhard*). The Examiner contends that *Reinhard* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

As mentioned above, independent claim 1, as amended, sets forth “a piston disposed inside said sidewall of said barrel to define a fluid chamber between said piston and said second opening that is in fluid communication with said second opening”, and that a periphery of the piston “provides a fluid seal with said axial grooves to inhibit fluid leakage from said fluid chamber between said piston and said inwardly-facing surface as said piston is advanced toward said second opening to dispense the fluid from said fluid chamber through said second opening”.

In contrast, *Reinhard* discloses a syringe barrel (1) with grooves (5) that are localized over a short distance axially between the openings at the opposite ends of the syringe barrel (1) and near the center of the barrel (1). The grooves (5) function to permit the stored liquid in chamber (3a) to bypass the piston (11) and mix with a dry component in chamber (2a), but only when the piston (11) is advanced relative to the barrel (1) to the location of the grooves (5). *See*

col. 6, lines 23-42. When the periphery of the piston (11) loses its fluid seal with the inwardly-facing surface of the barrel (1) and grooves (5), the grooves (5) function as flow channels to permit the liquid in chamber (3a) to flow past the piston (11) and mix with the dry component in chamber (2a). Moreover, the fluid chamber, which is between the piston (11) and the opening in the head (4) from which the fluid is dispensed, is not in fluid communication with the opening in the head (4). In addition, the grooves (5) in *Reinhard* are not contacted by the fluid when the fluid chamber is filled with fluid.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because of the aforementioned deficiencies, *Reinhard* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6-8, 18-20, and 22-25 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Reinhard*.

Claims 1, 3, 6-8, 18-20, and 22-27 over Nissho

Claims 1, 3, 6-8, 18-20, and 22-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by JP08-57051 to Nissho Co. Ltd. (hereinafter *Nissho*). The Examiner contends that *Nissho* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

*Nissho* fails to disclose “a plurality of axial grooves defined in said inwardly-facing surface” of the syringe sidewall. The Examiner states in the Office Action that roughening the inside surface of a syringe, as in *Nissho*, “will inherently produce microscopic grooves” that “extend at least partially in an axial direction and can therefore be considered axial grooves”.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support his determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Here, the Examiner fails to provide such a basis in fact and merely supplies a conclusion.

Specifically, the Examiner’s line of reasoning is not objective that draws a conclusion that the roughening in *Nissho* necessarily provides the axial grooves as set forth in Applicants’ claim 1. Instead, the Examiner is speculating and relying on subjective assumptions when concluding that the microscopic grooves in *Nissho* are necessarily arranged and aligned to provide the axial grooves set forth in claim 1. *Nissho* fails to disclose any fabrication process that would necessarily provide this result. It is at least equally probable that the microscopic grooves are not arranged and aligned to provide the claimed axial grooves that extend “substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said second opening”. Hence, the microscopic grooves in *Nissho* do not necessarily provide the claimed axial grooves. For this reason alone, independent claim 1 is patentable.

Because claims 3, 4, 6-8, 18-20, and 22-26 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above.

Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Nissho*.

Claims 1, 3-8 and 18-27 over Wyatt

Claims 1, 3-8 and 18-27 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Pub. No. 2005/0221035 to Wyatt (hereinafter Wyatt). The Examiner contends that Wyatt shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Similar to *Nissho*, the Examiner's line of reasoning is not objective that draws a conclusion that the roughening in Wyatt necessarily provides the axial grooves as set forth in Applicants' claim 1. Instead, the Examiner is speculating and relying on subjective assumptions when concluding that the microscopic grooves in Wyatt are necessarily arranged and aligned to provide the axial grooves set forth in claim 1. Wyatt fails to disclose any fabrication process that would necessarily provide this result. It is at least equally probable that the microscopic grooves are not arranged and aligned to provide the claimed axial grooves that extend "substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said second opening". Hence, the microscopic grooves in Wyatt do not necessarily provide the claimed axial grooves. For this reason alone, independent claim 1 is patentable.

Because claims 3-8 and 18-26 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by Wyatt.

### **Rejection of Claims under 35 U.S.C. § 103(a)**

#### **Claims 5 and 21**

Claims 5 and 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Nissho*. Applicants submit that dependent claims 5 and 21 are patentable for at least the same reasons as independent claim 1. To establish a *prima facie* case of obviousness, the prior art references being combined must teach or suggest all the claim limitations. Furthermore, dependent claims 5 and 21 each recites a unique combination of elements not disclosed or suggested by *Nissho*.

#### **Claim 9**

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown*, *Bachynsky*, *Reinhard*, *Wyatt*, or *Nissho* in view of U.S. Patent No. 4,846,796 to Carrell et al. (hereinafter *Carrell*). Applicants submit that dependent claim 9 is patentable for at least the same reasons as independent claim 1. To establish a *prima facie* case of obviousness, the prior art references being combined must teach or suggest all the claim limitations. Furthermore, dependent claim 9 recites a unique combination of elements not disclosed or suggested by the combination of *Brown*, *Bachynsky*, *Reinhard*, *Wyatt*, or *Nissho* with *Carrell*.

### **New Claims**

Claims 30-32 have been submitted as new claims that recite unique combinations of elements not disclosed or suggested by the art of record.

### **Conclusion**

Applicants have made a bona fide effort to respond to each and every requirement set forth in the Office Action. In view of the foregoing remarks, this application is submitted to be



in complete condition for allowance. Accordingly, a timely notice of allowance to this effect is earnestly solicited. In the event that any issues remain outstanding, Applicants invite the Examiner to contact the undersigned to expedite issuance of this application.

Applicants do not believe any fees are due in connection with filing this communication other than a one month time extension and a fee for a Request for Continued Examination. If, however, any petition or additional fees are necessary because of this communication, the Commissioner is hereby authorized to charge any under-payment or fees associated with this communication or credit any over-payment to Deposit Account No. 23-3000.

Respectfully submitted,

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